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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/099,738	03/15/2002	Christian A. Heid	4498C1	5560
22896	7590	03/04/2004	EXAMINER	
MILA KASAN, PATENT DEPT. APPLIED BIOSYSTEMS 850 LINCOLN CENTRE DRIVE FOSTER CITY, CA 94404			TUNG, JOYCE	
			ART UNIT	PAPER NUMBER
			1637	

DATE MAILED: 03/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action	Application No. 10/099,738	Applicant(s) HEID ET AL.	
	Examiner Joyce Tung	Art Unit 1637	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 29 January 2004 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.
- ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☒ A Notice of Appeal was filed on 29 January 2004. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
 - (b) ☐ they raise the issue of new matter (see Note below);
 - (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
 - (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____.

3. ☐ Applicant's reply has overcome the following rejection(s): _____.
4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: see the attached.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: _____.

Claim(s) objected to: _____.

Claim(s) rejected: 1-31.

Claim(s) withdrawn from consideration: _____.

8. ☐ The drawing correction filed on _____ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☒ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). 527,2003
10. ☐ Other: _____

Following the response filed 1/29/2004, the claims 1-31 are pending.

1. Claims 1-16, 23 and 26-31 remain rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Aoyagi et al. (5,952,202).

The response argues that the language "external control" is not intended use and it is an element and limitation of the claimed invention in that the external control is in a separate reaction. However, the language describes the way to use the polynucleotide. Since there is no structural distinction between the external control polynucleotide of the instant invention and the internal control polynucleotide of Aoyagi et al., the polynucleotide of Aoyagi et al. is equivalent to the polynucleotide recited in claim 1.

The response further argues that Aoyagi et al. do not teach the element "wherein the forward primer and the detectable probe are separated by 0-5 nucleotides when hybridized to the external control polynucleotide, or its complements and the reverse primer and the detectable probe are separated by 0 to 5 nucleotides when hybridized to the external control polynucleotide, or its complement. The teachings of Aoyagi et al. do not mention the exact distance(s) between the forward/reverse primer(s) from the detectable probe. However, it is clear that there is a teaching (See at least fig. 1) as regards the placement (i.e. hybridization positions) of the forward/reverse primers) in relation to the detectable probe. In the absence of an unexpected result, it is the examiner's position that it would have been prima facie obvious to ordinary artisan at the time of the instant invention to hybridize the forward/reverse primer(s) to the template and/or complement thereof at any distance from the hybridization position of the detectable probe so long as they were flanking the hybridization position of the detectable probe

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and as long as the distance was compatible with the assay reagents capabilities. The rejection is maintained.

2. Claims 24-25 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Aoyagi et al (5,952,202).

As discussed in section 1 above regarding the limitations of claim 1, with the same reasons, the rejection is maintained.

3. Claims 18-21 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Aoyagi et al. (5,952,202) as applied to claims 1-16, 23 and 26-31 above, and further in view of Kutyaavin et al. (5,801,155).

As discussed in section 1 above regarding the limitations of claim 1, with the same reasons, the rejection is maintained.

4. Claim 17 remains rejected under 35 U.S.C. 103(a) as being unpatentable over Aoyagi et al. (5,952,202) as applied to claims 1-16, 23 and 26-31 above, and further in view of Livak et al. (5,538,848).

As discussed in section 1 above regarding the limitations of claim 1, with the same reasons, the rejection is maintained.

5. Claim 22 remains rejected under 35 U.S.C. 103(a) as being unpatentable over Aoyagi et al. (5,952,202) as applied to claims 1-16, 23 and 26-31 above, and further in view of Williams et al. (6232,075).

As discussed in section 1 above regarding the limitations of claim 1, with the same reasons, the rejection is maintained.

Summary

6. No claims are allowable.
7. Any inquiries concerning this communication or earlier communications from the examiner should be directed to Joyce Tung whose telephone number is (703) 305-7112. The examiner can normally be reached on Monday-Friday from 8:00 AM-4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached at (703) 308-1119 on Monday-Friday from 10:00 AM-6:00 PM.

Any inquiries of a general nature or relating to the status of this application should be directed to the Chemical/Matrix receptionist whose telephone number is (703) 308-0196.

8. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Art Unit 1637 via the PTO Fax Center located in Crystal Mall 1 using (703) 305-3014 or 308-4242. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989).

Joyce Tung *JT*
February 24, 2004



**ETHAN WHISENANT
PRIMARY EXAMINER**